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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,292	08/27/2001	Naoki Shinozuka	159-68	4014

23117 7590 07/03/2003  
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EXAMINER

GITOMER, RALPH J

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 07/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/914,292

Applicant(s)  
Shinozuka et al.

Examiner  
Ralph Gitomer

Art Unit  
1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Mar 26, 2003
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

The amendment received 3/26/2003 has been entered and claims 1-8 are currently pending in this application. The amendment to the specification is acceptable.

5 The Terminal Disclaimer received 3/26/2003 has not been accepted because the patent to which it is directed is not the primary patent of the rejection. Therefor, the rejection of claims 1-8 under obviousness double patenting is maintained.

10 In view of the amendments to the claims, the rejection of record under 35 USC 112, second paragraph, is hereby withdrawn. However, see the new rejection below directed to the new claims.

15 Claim 8 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

20 New claim 8 includes the limitation of three components are individually immobilized on the electrode system. On page 12 of the present specification, buffer, 1-methoxy PMS was adsorbed on the electrodes, WST-1 was adsorbed on a carrier. This does not provide written description for the new claim.

The rejection of record of claims 4 and 5 under 35 USC 102(b) over Burd is maintained.

Applicant's arguments filed 3/26/2003 have been fully considered but they are not persuasive.

5 Applicants argue that the present inventors have found that upon application of a high potential with NBT, electrolysis of fructosamine is affected by contaminants in the sample. Instead, employing WST-1 induces less influence by contaminants. Also, WST-1 and formazan are more water soluble than NBT.

10 It is the examiner's position that much of applicants' arguments are centered upon unclaimed limitations. It is respectfully submitted that in order for evidence of unexpected results to be sufficient to rebut a prima facie case of obviousness, the evidence must be commensurate in scope with the  
15 claims.

The rejection of record of claims 1-3, 6-8 under 35 USC 103(a) over the combination of Burd in view of Ishiyama is maintained.

20 Applicant's arguments filed 3/26/2003 have been fully considered but they are not persuasive.

Applicants argue that EP 0908453 published a paper about WST-1, neither of which are made of record and the citation is too incomplete for the examiner to obtain it. It was believed  
25 that the formation of a formazan from a tetrazolium salt is an

irreversible reaction and would then not lend itself for electrochemical detection.

5 It is the examiner's position that on page 11 of the present specification, ~~the~~ The tetrazolium salt is not particularly restricted, so long as it can form formazan. ~~the~~ The specification does not indicate any criticality regarding the selection of the tetrazolium. Burd teaches in column 6 a number of tetrazolium compounds for the stated function. Claim 1 states the formazan  
10 formed is water soluble but no degree of solubility is claimed. Only new claims 6 and 7 include any limitations directed to a specific tetrazolium compound. The selection of the specific tetrazolium compound of claims 6 and 7 would have been obvious in view of Burd who teaches a number of tetrazolium compounds. To  
15 select a known compound for its known function with the expected result would have been obvious.

Claims 6-7 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point  
20 out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

~~Indohenyl~~ is queried.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

The following prior art pertinent to applicant's disclosure is made of record and not relied upon:

Iwata (6,130,054) with a filing date of 12/1998, teaches various tetrazolium salts of various solubilities including WST-1.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (703) 308-0732. The examiner can normally be reached on Tuesday-Friday from 8:00 am - 5:00 pm. The examiner can also be reached on alternate Mondays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (703) 308-4743. The fax phone number for this Art Unit is (703) 308-4556. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235. For 24 hour access to patent application information 7 days per week, or for filing applications electronically, please visit our website at [www.uspto.gov](http://www.uspto.gov) and click on the button Patent Electronic Business Center for more information.



Ralph Gitomer  
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